



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/806,650 | 04/02/2001 | Masato Nagaoka | 01192/HG | 3324 |

1933 7590 05/30/2003

FRISHAUF, HOLTZ, GOODMAN & CHICK, PC
767 THIRD AVENUE
25TH FLOOR
NEW YORK, NY 10017-2023

[REDACTED] EXAMINER

MAIER, LEIGH C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1623 | 8 |

DATE MAILED: 05/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | |
|--|--------------------------------------|--------------------------------|
| | Application No. 09/806,650 | Applicant(s) Nagaoka |
| | Examiner Leigh Maier | Art Unit 1623 |



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on election filed March 19, 2003
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above, claim(s) 6 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5 and 7 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on Apr 26, 2001 is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

Art Unit: 1623

DETAILED ACTION

Election/Restriction

Applicant's election of Group I in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In the original restriction requirement, Applicant was requested to state for the record if claims 4 and 5 were intended to be composition claims or method claims. Applicant has replied that the claims are intended to be compositions. As such, they have been combined with the claims of Group I. Claim 6 has been withdrawn from consideration. However, upon allowance of a product, claim(s) drawn to a method of making the allowed product (commensurate in scope with said product) will be rejoined.

Claim Objections

Claims 4 and 5 are objected to because of the following informalities: "Pharmaceutically" is misspelled in both claims. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1623

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by WALTON et al (US 4,489,065).

WALTON discloses a number of conjugates comprising an antibacterial substance covalently attached to chondroitin or chondroitin sulfate. See examples. The reference further discloses a pharmaceutical composition comprising a chondroitin sulfate/chloramphenicol conjugate. See example 22. The composition meets the structural limitations of the claim. Claims 4 and 5 recite intended use, but this is not a patentable limitation.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

Art Unit: 1623

evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over WALTON et al (US 4,489,065) as applied to claim 1, 4, and 5 above, and further in view of DADEY (WO 97/37680).

The invention is drawn to an antibacterial agent comprising a sulfated polysaccharide or oligosaccharide chemically bonded to an antibacterial substance. Claim 3 recites particular (poly/oligo)saccharide species.

WALTON teaches as set forth above. The reference teaches that the conjugates have utility for the controlled release of the therapeutic agent. See col 1-2. The reference does not teach the species recited in claim 3.

DADEY teaches that carrageenan is a functional equivalent of chondroitin sulfate in the preparation of (poly/oligo)saccharide-drug conjugates. See page 14, lines 15-30; page 12, lines 3-12; and claim 3.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute other polyacidic (poly/oligo)saccharides, such as those taught

Art Unit: 1623

by DADEY. One of ordinary skill would expect success in preparing these conjugates for their utility as pro-drugs for controlled release.

Claims 1-3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over DOMB et al (US 6,011,008) in view of JOSEPHSON et al (US 5,336,506).

The invention is as set forth above. Claim 2 recites that the (oligo/poly)saccharide is bonded to the antibacterial substance via a carbon derived from an aldehyde group. Claims 3 and 7 recite (oligo/poly)saccharide species, such as fucoidan.

DOMB teaches a conjugation of mitomycin to oxidized arabinogalactan. See Example III. Figure 1 illustrates the process with an internal oxidation, not one at the reducing end. However, this process would result in a number of products, with attachment at the reducing end expected to be included. These conjugates have utility in treating disorders, such as microbial infection. See col 2, lines 38-43. The reference does not teach sulfated (oligo/poly)saccharides.

JOSEPHSON teaches that arabinogalactan and fucoidan are functional equivalents for the efficient delivery of therapeutic agents. See col 4, lines 24-28. The reference further teaches the preparation of conjugation of therapeutic agents to lower molecular weight hydrolysis products. See col 4, lines 61-68.

It would have been obvious to one having ordinary skill in the art to prepare a conjugate comprising an antibiotic, such as mitomycin, and fucoidan or a lower molecular weight oligosaccharide derivative. One of ordinary skill would reasonably expect success in preparing

Art Unit: 1623

these conjugates by covalent attachment by reaction of the antibiotic to an aldehyde derived from oxidation of the fucoidan (or oligosaccharide derivative) for the art-disclosed utility of treating microbial infection.

Claims 1-3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over DOMB et al (US 6,011,008) in view of JOSEPHSON et al (US 5,336,506) in further view of DADEY (WO 97/37680).

The invention is as set forth above. Claims 3 and 7 recite the use of carrageenan or oligosaccharide derivatives.

DOMB and JOSEPHSON teach as set forth above. The references do not teach the use of carrageenan.

DADEY teaches as set forth above. The reference establishes that carrageenan has utility in the preparation of (poly/oligo)saccharide-drug conjugates.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute carrageenan (or an oligosaccharide derivative) in the process described above to prepare a conjugate for the treatment of a microbial disorder. One of ordinary skill would reasonably expect success in substituting another galactose-based polysaccharide, such as carrageenan, for arabinogalactan.

Art Unit: 1623

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Monday-Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (703) 308-4624, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.



Leigh C. Maier
Patent Examiner
May 28, 2003